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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants: A.G. DAIFOTIS et al.

DEC 21 2000

Serial No. 09/445,837

Filed: December 13, 1999

For: METHOD FOR INHIBITING BONE  
RESORPTION

TECH CENTER 1600/2900

Art Unit: 1614

Examiner: T. Criares

Assistant Commissioner for Patents  
Washington, D.C. 20231

JAN 13 2000

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

TECH CENTER 1600/2900

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application.

This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK &amp; CO., INC.

By

Date

11/7/00



# INFORMATION DISCLOSURE STATEMENT

4. Copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

U. S. SERIAL NUMBER	RELATED APPLICATION	
	FILING DATE	MERCK CASE

upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

5. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to a first Official Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after receipt of the first Office Action on the merits, but before Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of the statement.

Respectfully submitted,

By: Anthony D. Sabatelli

Attorney \_\_\_\_\_ For Applicant(s)

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Date: January 7, 2000

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Sheet

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of

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**COMPLETE IF KNOWN****Application Number**

09/445,837 .

**Filing Date**

December 13, 1999

**First Named Inventor**

A.G. DAIFOTIS et al.

Group Art Unit

1614

Examiner Name

T. Criares

Attorney Docket Number

20002YP

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number Kind Code (if known)		
			WO 95/30421	CIBA GEIGY AG	11/16/1995
			WO 96/17616	SANOFI	06/13/1996
			WO 94/00129	PROCTER & GAMBLE	01/06/1994
			WO 94/00130	PROCTER & GAMBLE	01/06/1994
			WO 94/21242	PROCTER & GAMBLE	09/29/1994
			EP 0 600 834 A1	CIBA GEIGY AG	06/08/1994
			WO 95/28145	PROCTER & GAMBLE	10/26/1995
			EP 0 274 158	NORWICH EATON	07/13/1988
			WO 95/08331	MERCK FROSST CANADA INC.	03/30/1995
			WO 95/28936	MERCK & CO., Inc.	11/02/1995

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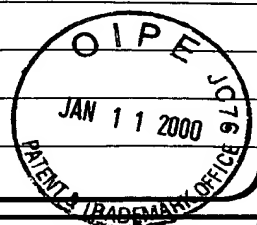
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**COMPLETE IF KNOWN**

Application Number	09/445,837
Filing Date	December 13, 1999
First Named Inventor	A.G. DAIFOTIS et al.
Group Art Unit	1614
Examiner Name	T. Criares
Attorney Docket Number	20002YP



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**OTHER NON PATENT LITERATURE DOCUMENTS**

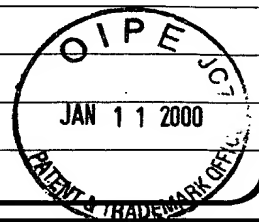
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Lunar News, April 1997, "Update: Bisphosphonate", pp. 30-32
	AB	Gertz et al., Osteoporosis Int. (1993), Suppl. 3: S13-16, "Clinical pharmacology of alendronate sodium"
	AC	Gertz et al., Clin. Pharm. Ther. (1995), Vol. 58, pp. 288-98, "Studies of the oral bioavailability of alendronate"
	AD	Singer et al., Advances in Endocrin. & Metab., Vol. 6 (1995), pp. 259-288, "Bisphosphonates in the treatment of disorders of mineral metabolism"
	AE	Lieberman et al., N. Eng. J. of Medicine, Vol. 333 (1995), pp. 1437-1443, "Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal ..."
	AF	Bankhurst et al., Arthritis and Rheumatism, Vol. 38, No. 9, Suppl. 1 (1995), S359, "Three-year treatment with alendronate prevents fractures in women with postmenopausal ..."
	AG	de Vernejoul et al., Calcified Tissue Int'l, Vol. 40 (1987), pp. 160-165, "Different schedules of administration of (3-amino-1-hydroxypropylidene)-1,1-bisphosphonate induce different changes ..."
	AH	Lufkin et al., Osteoporosis Int'l. (1994), Vol. 4, pp. 320-322, "Pamidronate: An unrecognized problem in gastrointestinal tolerability"
	AI	De Groen et al., N. Eng. J. of Medicine (1996), Vol. 335, pp. 1016-1021, "Esophagitis associated with the use of alendronate"
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	AK	Liberman et al., (correspondence), N. Eng. J. of Medicine (1996), Vol. 335, pp. 1069-1070, "Esophagitis and alendronate"
	AL	Chesnut et al., Am. J. of Medicine, Vol. 99 (1995), pp. 144-152, "Alendronate treatment of the postmenopausal osteoporotic woman ..."
	AM	Cassidy et al., Digestive Diseases and Sciences, Vol. 37 (1992), pp. 1206-1211, "continuous versus intermittent acid exposure in production of esophagitis in feline model"
	AN	Mortensen et al. J. of Bone Min. Res., (1995), Vol. 10, Suppl. 1, p. S140, "Prevention of early postmenopausal bone loss by risedronate"
	AO	Melsen et al., Osteoporosis, Chapt. 60 (1996), pp. 1145-1158, "ADFR - The concept and its performance"

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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.  
Draw line through citation if not in conformance and not considered.  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***(use as many sheets as necessary)***COMPLETE IF KNOWN**

Application Number	09/445,837
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Examiner Name	T. Criares
Attorney Docket Number	20002YP



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**OTHER NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AP	Thompson et al., J. of Bone & Min. Res., Vol. 7 (1992), pp. 951-960, "The bisphosphonate, alendronate, prevents bone loss in ovariectomized baboons"
	AQ	Balena et al., J. Clin. Invest., Vol. 92 (1993), pp. 2577-2586, "The effects of 2-year treatment with the aminobisphosphonate alendronate on bone metabolism, bone histomorphometry, and bone strength in ovariectomized nonhuman primates"
	AR	Peter et al., Digestive Diseases & Sciences, Vol. 43 (1998), pp. 1009-1015, "Comparative study of potential for bisphosphonates to damage gastric mucosa of rats"
	AS	Peter et al., Digestive Diseases & Sciences, Vol. 43 (1998), pp. 1998-2002, "Esophageal irritation due to alendronate sodium tablets"
	AT	Filipponi et al., J. of Bone & Min. Res., Vol. 10 (1995), pp. 697-703, "Cyclical clodronate is effective in preventing postmenopausal bone loss: A comparative study with transcutaneous hormone replacement therapy"
	AU	McClung et al., Bone, Vol. 17 (1995), pp. 493S-496S, "Tiludronate therapy for Paget's disease of bone"
	AV	Seltenmeyer et al., Bone (NY), Vol. 20, No. 4, Suppl. (1997), pp. 114S, "A comparison of the antiresorptive potency of various bisphosphonates in vivo with their inhibitory effect in vitro on squalene synthase and cellular sterol synthesis"
	AW	Adachi et al., Today's Therapeutic Trends, Vol. 14, No. 1 (1996), pp. 13-24, "Osteoporosis -- its diagnosis, management and treatment with a new oral bisphosphonate agent, etidronate"
	AX	Bell et al., Endocrine, Vol. 6(2) (1997), pp. 203-206, "Bisphosphonates in the treatment of osteoporosis"
	AY	Harris et al., J. of Clin. Endoc. & Metab., Vol. 76 (1993), pp. 1399-1406, "The effect of short term treatment with alendronate on vertebral density and biochemical markers of bone ..."

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